K072273

SUMMARY

On behalf of Takara Belmont USA; Schiff & Company, West Caldwell, NJ has submitted this 510k Pre-market notification for QUOLIS 5000 Series Dental Unit (Dentist Chair for diagnosis, treatment and performance of dental procedures). The device is a modification of the existing device, Belmont 2000 cleared as K010799. This Dental Unit and Accessories are intended for the Dentists, Hygienists, and Dental assistants for traditional and normal patient treatment procedures in the dentist office. The design, functioning, and positioning of the unit and accessories are similar to most other dental units manufactured for this specific purpose over the past twenty five years.

DEC 3 0 2007

Device Detail:

Device Class:	CFR 872.6640 Identified device, Dental Operative Unit and Accessories as Class 1, Reserve.
Trade or proprietary name:	BELMONT QUOLIS 5000 SERIES DENTAL UNIT
Common or usual name:	Dentist's Unit
Classification Name:	Dental Operative Unit and Accessories
Device Listing No.:	048314
Classification:	CFR 872.6640 Identified device, Dental Operative Unit and Accessories, as Class 1, Reserve.
Performance Standards:	IEC 60601-1, ISO-7494-2:2003, ISO-7494-1:2004, ISO 60601-1
Labeling:	Copies are attached.

Establishment Detail:

Establishment Registration Number: 96114485

TAKARA BELMONT USA, INC.
BELMONT Equipment Division
101 Belmont Drive
Somerset, New Jersey 08873-1204

Performance compliance:

IEC 60601-1, ISO-7494-2:2003, ISO-7494-1-2004, ISO 60601-1

Substantially Equivalent:

This Dental Unit and accessories , based on being "Substantially Equivalent" to the Belmont Dental Unit , Model 2000 series and Model 6000 series, as indicated in the Belmont 510k, Pre-market notification submission dated March 7, 2000, K000799. Comparison of QUOLIS 5000 dental unit and Belmont 2000 Series Dental Unit as presented in attachment 2 indicates that both units are substantially equivalent.

Installation, Operating Instruction, Care and Maintenance are attached.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

Takara Belmont USA, Incorporated
C/O Robert Schiff, Ph.D., RAC, CQA
President
Schiff & Company, Incorporated
1129 Bloomfield Avenue
West Caldwell, New Jersey 07006

Re: K072273
Trade/Device Name: Belmont, Dental Unit & Accessories, Quolis 5000 Series
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: NRD
Dated: December 14, 2007
Received: December 17, 2007

Dear Dr. Schiff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

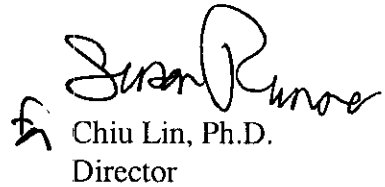
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: BELMONT, DENTAL UNIT & ACCESSORIES, QUOLIS 5000 SERIES

Indications For Use:
Dental Unit and Accessories are intended for the Dentists, Hygienists, and Dental assistants for traditional and normal patient treatment procedures in the dental operatory.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072273